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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	64095753 (27839-143)	7018
45736 7590 12/01/2008 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102				
EXAMINER CHANNAVAJALA, LAKSHMI SARADA				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
12/01/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary

Application No.

10/803,819

Applicant(s)

SYVERSON ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13 and 15-60 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12, 13 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of RCE, amendment and response all dated 8-11-08 is acknowledged.

Claims 1-10, 12, 13 and 15-60 are pending.

Claims 11 and 14 are canceled.

Claims 5, 12, 13 and 26-60 are withdrawn as nonelected.

Claims 1-4, 6-10 and 15-25 have been considered for examination.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-11-08 has been entered.

In response to the amendment, the following rejection of record has been vacated:

1. Claims 7 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Claims 7 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. **The following rejection of record has been maintained:**

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-10 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (J. Clin. Microbiol. 1987) and Lambert (J Applied Microbiol.) in view of US 5,612,045 to Syverson or Syverson in view of Robbins et al and Lambert.

Robbins et al studied the production of toxic shock syndrome toxin 1 by *Staphylococcus aureus* (*S. aureus*) as determined by tampon-disk-membrane- agar method. Robbins et al teach that the occurrence of toxic shock syndrome due to infection or colonization of *S. aureus* and its association with the use of tampons in menstruating women (page 1446, col. 1). Robbins et al observed that tampons of different materials supported characteristic levels of growth and toxin production by *S. aureus* (table 1, page 1447 and results on page 1448, col. 1). Robbins et al conclude that the tampons provide a fibrous surface for heavy colonization by *S. aureus* and also observed a decrease in toxic shock syndrome toxin (TSST) production by inhibiting the growth of *S. aureus* by additives such as surfactants (last column on page 1449).

Robbins fails to teach the first active ingredient of the instant claims.

Lambert studied the minimum inhibitory concentrations of different antimicrobial compounds against *S. aureus* and observed that phenoxyethanol and phenyl ethyl alcohol (designated as PoE and PeA respectively) are effective against *S. aureus* (abstract, page 276, col. 1, table 2, page 278, col. 2 and Discussion), even though the

MICs vary with the inoculum levels. Lambert does not teach phenoxyethanol on anon-absorbent article as claimed in the instant invention.

Syversen teaches absorbent articles and non-absorbent articles (col. 3, lines 55-60) such as catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by *S. Aureus* (abstract, col. 3, lines 40-60). The compounds of Syversen comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). Syversen teaches including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Lambert, which is effective against *S. aureus*, together with ether compounds in the articles of Syversen because Robbins et al teach *S. aureus* causes toxic shock syndrome in women using tampons and Syversen suggests employing compounds that for inhibiting toxic shock syndrome (caused by *S. aureus*) on devices such as tampons. Alternatively, Syversen does not teach the claimed first active agent. However, it would have been obvious for one of an ordinary skill in the art at time of the instant invention to incorporate phenoxyethanol of Lambert in the article of Syversen because Lambert teaches phenoxyethanol is effective against *S. aureus* and Robbins teaches inhibition of *S. aureus* toxin production by adding the inhibitors on tampons. In this regard, Robbins et al show that the toxin production does not depend on the type of article (tampon) used. Further, optimizing the

amounts of ether (of Syverson) and phenoxyethanol of Lambert, with an expectation to provide the optimum inhibitory effect of *S. aureus* toxin production would have been within the scope of a skilled artisan.

Response to Arguments

5. Applicant's arguments filed 8-11-08 have been fully considered but they are not persuasive.

Applicants' argue that Robbins et al studied the influence of commercially available exotoxin production by *S. aureus* and that the toxin production increased with all the tampons when blood was added to the agar medium concluding that one function of tampon may be supporting vaginal infection. Applicants state that Robbins et al showed that the surfactant Aqualon had little effect on the growth or TSST-1 production whereas a combination of deodorant and Aqualon shows >50% decrease in TSST-1 recovery. Applicants' arguments are not persuasive because the teachings of Robbins are pertinent and analogous to that of the instant application. Applicants agree that according to Robbins, one function of tampons may be to support the vaginal infection by supplying a fibrous surface for heavy colonization and to provide a sufficiently aerobic environment for toxin production.

Applicants argue that Lambert discloses a method of examining the effect of inoculum size on the degree of inhibition observed with respect to inhibitor concentration. Specifically, the inoculum size dependencies of phenethyl alcohol, phenoxyethanol, p-chloro-m- cresol, trichloro-phenol, thymol, and

dodecyltrimethylammonium bromide against S. aureus were analyzed. It is argued that for all inhibitors examined, it was found that at lower inoculum levels, there was a greater biocidal effect, whereas at higher inoculum levels, there was a greater degree of quenching of the biocide, causing the inhibitor to act more as a simple (sublethal) inhibitor. Applicants agree that the method developed in Lambert may be used to quantify the effect in the region between reversible and irreversible damage, or sublethal injury to cell death and that according to Lambert that phenethyl alcohol is a better inhibitor than phenoxyethanol against S. aureus. Applicants' arguments are not persuasive because the teachings of Lambert are analogous to those of Robbins, Syverson and instant application. Further, known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. In this regard, Lambert teaches different compounds and their effect on the reversible and irreversible damage to various inoculum levels of S. aureus.

Applicants argue that both Robbins et al. and Lambert fail to disclose the use of phenoxyethanol (or any compound having the structure of the first active ingredient) in combination with a second active ingredient on a non-absorbent substrate being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche for insertion into the vagina for inhibiting exoproteins from Gram positive bacteria as required in claim 1.

2. However, Robbins was only cited for the fact that the occurrence of toxic shock syndrome due to infection or colonization of S. aureus and its association with the use

of tampons in menstruating women. With respect to Lambert, applicants' argument that phenethyl alcohol is a better inhibitor than phenoxyethanol against *S. aureus*, the arguments are not persuasive because the teaching of Lambert that phenethyl alcohol is superior to phenoxyethanol does not lead to the conclusion that the latter is not effective in inhibiting *S. aureus*.

3. It is argued that Syverson teaches absorbent articles and not non-absorbent articles. Applicants' arguments are not persuasive because Syverson teaches both absorbent and non-absorbent articles with *S. aureus* exoprotein inhibiting compounds. Applicants' attention is directed to col. 3, lines 50-60, where it is stated that the tampons may be absorbent or non-absorbent. While Syverson prefers absorbent fibers, it is to be noted that the prior art teachings are not limited to preferred embodiments and instead the teachings should be considered as a whole. Applicants argue that the Office is misconstruing the reference in particular, although Syverson discloses at column 3, lines 56-58, that "the tampon may be made of various fiber blends including both absorbent and nonabsorbent fibers," (emphasis added) Syverson does not disclose that the tampon itself is nonabsorbent. It is argued that the tampon as described in Syverson would not be effective for its intended use if the assembled tampon was non-absorbent and hence, Syverson does not describe or suggest a non-absorbent substrate selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche.

4. The arguments are not persuasive because instant claim 1 recites- *An exoprotein inhibitor for inhibiting the production of exoproteins from Gram positive bacteria in and*

around the vagina comprising a non-absorbent substrate for insertion into a vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche, the non-absorbent substrate having deposited thereon an

The above claim nowhere states that the substrate as well as fibers that make up the substrate is non-absorbent. Instant "comprising" language allows for the presence of absorbent fibers of Syverson.

Furthermore, the argument that the tampon as described in Syverson would not be effective for its intended use if the assembled tampon was non-absorbent is not supported by factual evidence nor applicants provided any showing that the article of Syverson is not suitable for instant use. However, arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

5. For the argument that both Robbins et al. and Lambert fail to disclose the use of phenoxyethanol (or any compound having the structure of the first active ingredient as required in claim i) on a non-absorbent substrate being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche for insertion into the vagina for inhibiting exoproteins from Gram positive bacteria, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Each of the cited references provides teachings that

upon combination render the instant invention obvious. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention that exoprotein inhibiting compounds may be applied on both absorbent as well as nonabsorbent articles and still achieve the desired inhibitory activity. One of an ordinary skill in the art would have been motivated to include phenoxyethanol of Lambert on the non-absorbent articles of Syverson with a reasonable expectation that phenoxyethanol is effective in inhibiting the exoprotein produced by *S. aureus* because Robbins admittedly teaches tampons support vaginal infections such as those caused by *S. aureus* by supplying a fibrous surface and that suggests inhibitors for inhibiting exoprotein production. It would have been reasonable for one of an ordinary skill in the art to expect that *S. aureus* exoprotein production can be inhibited by any inhibitor, including the phenoxyethanol of Lambert, to exhibit such activity.

6. Regarding the argument that for TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention, each of the references cited teach the inhibition of *S. aureus* and/or its toxins and Robbins and Syverson further teaches tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by *S. Aureus*. Thus, the combination of references provide the requisite TSM to arrive at the instant invention, with a reasonable expectation of inhibiting the protein produced by *S. aureus* with the compounds of

Lambert and Syverson by applying them on the substrates (non-absorbent) of Syverson.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
November 21, 2008